

In the Claims

Please amend the claims as follows.

1 Claims 1-4 (canceled).

1 5. (Previously added) A method for forming a pathway from a sub-intimal space
2 of a blood vessel into a true lumen of the blood vessel, comprising:

3 positioning a catheter system within the sub-intimal space at a position proximate
4 to a target entry site into the vessel true lumen, the catheter system including at least one
5 lumen in communication with at least one port in a distal region of the catheter system;
6 the catheter system further including an internal incising element that is translatable
7 across a portion of the port;

8 determining a radial position of the true lumen with respect to the port at the
9 target entry site from a position in the sub-intimal plane using an imaging device of the
10 catheter system; and

11 forming an incision in tissue separating the sub-intimal space from the true lumen
12 using the incising element, the incision having separate and distinct end points and
13 forming a pathway between the sub-intimal space and the true lumen, wherein the tissue
14 remains external to the port subsequent to forming the incision.

1 6. (Previously added) The method of claim 5, wherein the imaging device is a
2 rotational imaging device.

1 7. (Withdrawn) The method of claim 5, wherein the imaging device is an ultrasonic
2 device.

1 8. (Withdrawn) The method of claim 5, wherein the imaging device is an optical
2 coherence tomography (OCT) device.

- 1 9. (Withdrawn) The method of claim 5, wherein the incising element is integral to
2 the imaging device.
- 1 10. (Withdrawn) The method of claim 5, wherein the incising element is separate
2 from and arranged concentrically outside the imaging device.
- 1 11. (Previously added) The method of claim 5, wherein determining the radial
2 position includes use of an imaging device that is a fixed integral part of a body of the
3 catheter system.
- 1 12. (Withdrawn) The method of claim 5, wherein determining the radial position
2 includes use of a fluoroscopic marker on the catheter system.
- 1 13. (Withdrawn) The method of claim 12, wherein the fluoroscopic marker is
2 located on a body of the catheter system.
- 1 14. (Withdrawn) The method of claim 12, wherein the fluoroscopic marker is
2 located on one or more working elements of the catheter system.
- 1 15. (Previously added) The method of claim 5, further comprising evacuating fluid
2 from the sub-intimal space and securing the tissue separating the sub-intimal space from
3 the true lumen at the port by applying vacuum to the catheter lumen.
- 1 16. (Previously added) The method of claim 15, further comprising invaginating
2 the tissue separating the sub-intimal space from the true lumen into the port and into a
3 distal interior region of the catheter system upon application of the vacuum.
- 1 17. (Previously added) The method of claim 5, further comprising advancing a
2 working element into the true lumen through the incision.

1 18. (Previously added) The method of claim 17, wherein the working element
2 includes at least one of a guide wire and a cannula.

1 19. (Previously added) A method for forming a pathway from a sub-intimal space
2 of a blood vessel into a true lumen of the blood vessel, comprising:
3 positioning a catheter system within the sub-intimal space at a position proximate
4 to a target entry site into the vessel true lumen, the catheter system including at least one
5 lumen in communication with at least one port in a distal region of the catheter system,
6 the catheter system further including an internal incising element that is translatable
7 across a portion of the port; and
8 forming an incision in tissue separating the sub-intimal space from the true lumen
9 using the incising element, the incision having separate and distinct end points and
10 forming a pathway between the sub-intimal space and the true lumen, wherein the tissue
11 remains external to the port subsequent to forming the incision.

1 20. (Previously added) A method for forming a pathway from a sub-intimal space
2 of a blood vessel into a true lumen of the blood vessel, comprising:
3 positioning a catheter system within the sub-intimal space at a position proximate
4 to a target entry site into the vessel true lumen, the catheter system including at least one
5 lumen in communication with at least one port in a distal region of the catheter system,
6 the catheter system further including an internal excising element that is translatable
7 across a portion of the port;
8 determining a radial position of the true lumen with respect to the port at the
9 target entry site from a position in the sub-intimal plane using an imaging device of the
10 catheter system;
11 advancing the internal excising element along a portion of the port; and
12 excising an area of tissue separating the sub-intimal space from the true lumen
13 using the excising element, the excised area of tissue generating a pathway from the sub-
14 intimal space to the true lumen.

- 1 21. (Previously added) A method for forming a pathway from a sub-intimal space
2 of a blood vessel into a true lumen of the blood vessel, comprising:
3 positioning a catheter system within the sub-intimal space at a position proximate
4 to a target entry site into the vessel true lumen, the catheter system including at least one
5 lumen in communication with at least one port in a distal region of the catheter system,
6 the catheter system further including an internal excising element that is translatable
7 across a portion of the port;
8 advancing the internal excising element along a portion of the port; and
9 excising an area of tissue separating the sub-intimal space from the true lumen
10 using the excising element, the excised area of tissue generating a pathway from the sub-
11 intimal space to the true lumen.
- 1 22. (Previously added) A method for establishing a pathway through a chronic
2 total occlusion of a blood vessel, the pathway connecting a first region of a true lumen of
3 the blood vessel which is proximal to the occlusion to a second region of the true lumen
4 of the blood vessel distal to the occlusion via an extra-luminal pathway within the vessel,
5 comprising:
6 forming a track longitudinally from the first region of the true lumen through the
7 occlusion and into a sub-intimal space distal to the occlusion;
8 positioning a catheter system within the sub-intimal space using the track, the
9 catheter system including at least one lumen in communication with at least one port in a
10 distal region of the catheter system, the catheter system further including an internal
11 incising element that is translatable across a portion of the port;
12 determining a radial position of the true lumen with respect to the port using an
13 imaging device of the catheter system; and
14 forming an incision in tissue separating the sub-intimal space from the true lumen
15 using the incising element, the incision having separate and distinct end points and
16 forming a pathway between the sub-intimal space and the true lumen, wherein the tissue
17 remains external to the port subsequent to forming the incision.

1 23. (Previously added) A method for establishing a pathway through a chronic
2 total occlusion of a blood vessel, the pathway connecting a first region of a true lumen of
3 the blood vessel which is proximal to the occlusion to a second region of the true lumen
4 distal to the occlusion via an extra-luminal pathway within the vessel, comprising:
5 forming a track longitudinally from the first region of the true lumen through the
6 occlusion and into a sub-intimal space distal to the occlusion;
7 positioning a catheter system within the sub-intimal space using the track, the
8 catheter system including at least one lumen in communication with at least one port in a
9 distal region of the catheter system;
10 determining a radial position of the true lumen with respect to the port using an
11 imaging device of the catheter system;
12 applying a vacuum through the catheter lumen and the port, evacuating fluid from
13 the sub-intimal space and bringing the sub-intimal tissue into intimate contact with the
14 port; and
15 advancing a working element through the port and through the tissue separating
16 the sub-intimal space and the second region of the true lumen and generating a pathway
17 from the sub-intimal space to the second region of the true lumen.

1 Claims 24-42 (canceled).